K093577



# Summary of Safety and Effectiveness
# Liquichek Opiate Control

## 1.0 SUBMITTER

Bio-Rad Laboratories
9500 Jeronimo Road,
Irvine, California 92618-2017
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MAR 12 2010

### CONTACT PERSON

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Regulatory Affairs Specialist
Telephone: (949) 598-1467

### DATE OF SUMMARY PREPARATION

March 10, 2010

## 2.0 DEVICE IDENTIFICATION

| | |
|---|---|
| Product Trade Name: | Liquichek Opiate Control |
| Common Name: | Drug Mixture Control |
| Classifications: | Class I |
| Product Code: | DIF |
| Regulation Number: | 21 CFR 862.3280 |

## 3.0 DEVICE WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED

Liquichek Urine Toxicology Control (Levels S1E and S2E)
Bio-Rad Laboratories
Irvine, California

Docket Number: K022707

## 4.0 DESCRIPTION OF DEVICE

Liquichek Opiate Control is prepared from human urine with added drugs of abuse, metabolites of drugs of abuse, preservatives, stabilizers and constituents of animal origin. The control is provided in liquid form for convenience.

## 5.0 STATEMENT OF INTENDED USE

Liquichek Opiate Control is intended for use as a quality control urine to monitor the precision of laboratory urine toxicology testing procedures for the analytes listed in the package insert.

## 6.0 COMPARISON OF THE NEW DEVICE WITH THE PREDICATE DEVICE

Liquichek Opiate Control claims substantial equivalence to Liquichek Urine Toxicology Control currently in commercial distribution (K022707).

**Table 1.** Similarities and Differences between new and predicate device.

| Characteristics | Bio-Rad Liquichek Opiate Control (New Device) | Bio-Rad Liquichek Urine Toxicology Control (Predicate Device K022707) |
|---|---|---|
| | **Similarities** | |
| **Intended Use** | Liquichek Opiate Control is intended for use as quality control urine to monitor the precision of laboratory urine toxicology testing procedures for the analytes listed in this package insert. | Liquichek Urine Toxicology Control is intended for use as quality control urine to monitor the performance of laboratory urine toxicology enzyme immunoassay (EIA) screening procedures. |
| **Form** | Liquid | Liquid |
| **Matrix** | Urine | Urine |
| **Open Vial** | 30 days at 2-8°C | 30 days at 2-8°C |
| | **Differences** | |
| **Storage** (Unopened) | -20° to -70°C until expiration date | 2-8°C until expiration date |
| **Fill Volume** | 5 mL | 10 mL |
| **Analytes** | Claims for:<br>Buprenorphine<br>EDDP<br>Fentanyl<br>Methadone<br>6-Monoacetylmorphine (6-MAM, 6-AM)<br>Oxycodone | Claims for:<br>d-Methamphetamine<br>Secobarbital<br>Lormetazepam<br>11-Nor-Δ-9-THC-9-COOH<br>Benzoylecgonine<br>Ethanol<br>LSD<br>Methadone<br>Methaqualone Morphine (Free)<br>Phencyclidine<br>Propoxyphene<br>Nortriptyline<br>Creatinine<br>Specific Gravity<br>pH |
| | Does not claim:<br>d-Methamphetamine<br>Secobarbital<br>Lormetazepam<br>11-Nor-Δ-9-THC-9-COOH<br>Benzoylecgonine<br>Ethanol<br>LSD<br>Methaqualone<br>Morphine (Free)<br>Phencyclidine<br>Propoxyphene<br>Nortriptyline | Does not claim<br>Buprenorphine<br>EDDP<br>Fentanyl<br>6-Monoacetylmorphine (6-MAM, 6-AM)<br>Oxycodone |

## 7.0 SUMMARY OF PERFORMANCE DATA

Stability studies have been performed to determine the open vial and shelf life stability for the Liquichek Opiate Control. Product claims are as follows: to establish claims are as follows:

7.1 Open vial Stability: Once the control is thawed and opened, all analytes will be stable for 30 days when stored tightly capped at 2 to 8°C.

7.2 Shelf Life Stability: Three years when stored at -20 to -70°C.

Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Bio-Rad Laboratories
c/o Ms. Suzanne Parsons
Regulatory Affairs Specialist
9500 Jeronimo Road
Irvine, CA 92618-2017

MAR 1 2 2010

Re: k093577
Trade Name: Liquichek™ Opiate Control
Regulation Number: 21 CFR §862.3280
Regulation Name: Clinical toxicology control material.
Regulatory Class: Class I, reserved
Product Codes: DIF
Dated: January 08, 2010
Received: January 22, 2010

Dear Ms. Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use Form

510(k) Number (if known): K093577

Device Name: Liquichek™ Opiate Control

Indications for Use: Liquichek Opiate Control is intended for use as a quality control urine to monitor the precision of laboratory urine toxicology testing procedures for the analytes listed in the package insert.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K093577